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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,723	02/20/2004	Yuniko Shibata	249169US0	4185

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,723	SHIBATA, YUNIKO	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 07/29/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "low molecular weight" in claim 1,2 and 6 is a relative term which renders the claim indefinite. These terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what specific molecular weight or range of molecular weight is considered a "low molecular weight".

The phrase "wherein the ultraviolet ray to be irradiated"" in claim 5 is a phrase which renders the claim indefinite. More specifically, it is unclear how a ray can itself be irradiated".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs et al. (Radiation Research (1959), vol.11, pages 149-64).

In claim 1, applicant claims "A method for producing a low molecular weight glycosaminoglycan, which comprises irradiating a glycosaminoglycan with an ultraviolet ray. Balazs et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) (see abstract). The examiner considers the hyaluronic acid produced to be low molecular weight hyaluronic acid, since Balazs et al. disclose that the hyaluronic acid decreased in mol. weight and length. Furthermore, applicant's low molecular weight glycosaminoglycan is not characterized by any claimed specific molecular weight. Claim 2, which is drawn to the method according to claim 1, wherein light quantity of the ultraviolet ray is determined from molecular weight of a desired low molecular weight glycosaminoglycan on the basis of a direct proportional relationship between quantity of irradiated ultraviolet ray and reciprocal of molecular weight of low molecular weight glycosaminoglycan to be produced, is also anticipated by Balazs et al., since the claimed low molecular weight glycosaminoglycan is produced regardless of the light quantity of the ultraviolet ray used, and since said determined light quantity is not characterized by any given specific amount or units (see abstract). That is, the said determination of the light quantity is not considered a limitation, since it produces the same low molecular weight glycosaminoglycan which is not of any specifically claimed molecular weight value or amount. Furthermore, the

examiner considers the light quantity used by Balazs et al., to be the same as applicant's since it produces the same effect. Claim 3, which is drawn to the method according to claim 1, wherein the glycosaminoglycan is selected from the group consisting of hyaluronic acid, chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate and keratin sulfate, is anticipated by Balazs et al., since Balazs et al. use the glycosaminoglycan, hyaluronic acid (see abstract). Claim 5, which is drawn to a method of claim 1, wherein the ultraviolet ray to be irradiated has a wavelength of 250 to 450 nm, is anticipated by Balazs et al., since Balazs et al.'s hyaluronic acid product is formed with a maximum wave length at 2670 Å (267 nm) (see abstract).

Claims 1-3, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hvidberg et al. (Acta Pharmacologica et Toxicologica (1959), 15, 356-64).

In claim 1, applicant claims "A method for producing a low molecular weight glycosaminoglycan, which comprises irradiating a glycosaminoglycan with an ultraviolet ray. Hvidberg et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) (see abstract). The examiner considers the hyaluronic acid produced to be low molecular weight hyaluronic acid, since Hvidberg et al. disclose that the molecular weight hyaluronic acid products were about 1000 (see abstract). Furthermore, applicant's low molecular weight glycosaminoglycan is not characterized by any claimed specific molecular weight. Claim 2, which is drawn to the method according to claim 1, wherein light quantity of the ultraviolet ray is determined from molecular weight of a desired low molecular weight glycosaminoglycan on the basis of a direct proportional relationship between quantity of irradiated ultraviolet ray and reciprocal of molecular weight of low

molecular weight glycosaminoglycan to be produced, is also anticipated by Hvidberg et al., since the claimed low molecular weight glycosaminoglycan is produced regardless of the light quantity of the ultraviolet ray used, and since said determined light quantity is not characterized by any given specific amount or units (see abstract). That is, the said determination of the light quantity is not considered a limitation, since it produces the same low molecular weight glycosaminoglycan which is not of any specifically claimed molecular weight value or amount. Furthermore, the examiner considers the light quantity used by Hvidberg et al., to be the same as applicant's since it produces the same effect. Claim 3, which is drawn to the method according to claim 1, wherein the glycosaminoglycan is selected from the group consisting of hyaluronic acid, chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate and keratin sulfate, is anticipated by Hvidberg et al., since Hvidberg et al. use the glycosaminoglycan, hyaluronic acid (see abstract). Claim 5, which is drawn to a method of claim 1, wherein the ultraviolet ray to be irradiated has a wavelength of 250 to 450 nm, is anticipated by Hvidberg et al., since Hvidberg et al.'s hyaluronic acid product use light of wave length at 2550 Å (255 nm) (see abstract).

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Balazs et al. (Radiation Research (1959), vol.11, pages 149-64).

In claim 1, applicant claims "A method for producing a low molecular weight glycosaminoglycan, which comprises irradiating a glycosaminoglycan with an ultraviolet ray. In claim 4, applicant claims "The method according to claim 1, wherein temperature is maintained at 1 to 37°C during ultraviolet ray irradiation.

Balazs et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) (see abstract). The examiner considers the hyaluronic acid produced to be low molecular weight hyaluronic acid, since Balazs et al. disclose that the hyaluronic acid decreased in mol. weight and length. Furthermore, applicant's low molecular weight glycosaminoglycan is not characterized by any claimed specific molecular weight. Although Balazs et al. is silent about the temperature during the ultraviolet irradiation this does not mean that the temperature is not 1 to 37°C. Balazs et al. anticipate the claims if their the temperature is 1 to 37°C. Balazs et al. render the claims as being obvious if their temperature is substantially close to the claimed limitation of 1 to 37°C. In fact, one may deduce that Balaz et al. temperature would be about room temperature (approx. 25 °C), since such ultraviolet irradiation of samples are normally performed at room temperature.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hvidberg et al. (Acta Pharmacologica et Toxicologica (1959), 15, 356-64).

In claim 1, applicant claims "A method for producing a low molecular weight glycosaminoglycan, which comprises irradiating a glycosaminoglycan with an ultraviolet ray. In claim 4, applicant claims "The method according to claim 1, wherein temperature is maintained at 1 to 37°C during ultraviolet ray irradiation.

Hvidberg et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) (see abstract). The examiner considers the hyaluronic acid produced to be low molecular weight hyaluronic acid, since Hvidberg et al. disclose that the molecular weight hyaluronic acid products were about 1000 (see abstract). Furthermore, applicant's low molecular weight glycosaminoglycan is not characterized by any claimed specific molecular weight. Although Hvidberg et al. is silent about the temperature during the ultraviolet irradiation this does not mean that the temperature is not 1 to 37°C. Hvidberg et al. anticipate the claims if their the temperature is 1 to 37°C. Hvidberg et al. render the claims as being obvious if their temperature is substantially close to the claimed limitation of 1 to 37°C. In fact, one may deduce that Hvidberg et al. temperature would be about room temperature (approx. 25 °C), since such ultraviolet irradiation of samples are normally performed at room temperature. It should be noted that claim 6 appears to be free of the prior art of record

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

April 1, 2005.

ELVIS O. PRICE, PH.D.
PRIMARY EXAMINER